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SEMINAR ON CARDIAC VALVE REPLACEMENT—I

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Introduction: Valve Replacement: The First Quarter Century

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At the 16th Annual American College of Cardiology Conference held in Snowmass, Colorado in January 1985, a series of papers was presented on the current results of valve surgery. The presenters were Drs. Albert Starr, Alain Carpentier, Viking Björk, Marian Ionescu, Karl Victor Hall, Jack Matloff, John Relland and John Callaghan, a group of surgeons whose combined experience with the development of new valves and their subsequent advancement into worldwide cardiac surgical practice is unequaled.

The occasion provided an opportunity not only to create some order out of the confusing, rapidly proliferating array of valve choices, but also to reflect on how far we have come in the first quarter century of valve replacement. Thousands of closed valve operations had been performed before the first valve was replaced because replacement had to await the perfecting of cardiopulmonary bypass. After John Gibbon's first "pump" operation in October 1953 the repair of all cardiac defects became possible. But prosthetic valves still had to be developed.

Development of valve prostheses. Dr. Charles Hufnagel implanted caged ball valves and Dr. Gordon Murray sewed homografts into the descending aorta for the treatment of aortic regurgitation in the mid 1950s. These operations partially corrected the physiologic problems, but were not true valve replacements.

Dr. Albert Starr first replaced the mitral valve on the 21st of September 1960 (1). He was not alone in working on the problems of valve replacement. Bahnson, Binet, Björk, Beall, Barratt-Boyes, Carpentier, Harken, Ionescu, Kay, Ross, Smeloff and many others contributed new designs and techniques, expanding the frontiers of cardiac surgery.

That first exciting decade brought forth a flood of designs: ball valves, "toilet seats," butterfly flaps, single cusps and whole valves imitating the aortic valve; prostheses with round poppets, cone-shaped poppets and discs of various thicknesses made with a multitude of materials. Stellite, Teflon as a woven cloth or as a solid poppet, delrin, titanium pyrolite carbon, Silastic rubber and polypropylene are but a few of those materials. And, at the same time, tissue valves, homografts and xenografts were used with increasing success. The successful 23 year results of Barratt-Boyes (personal communication, 1985) with fresh homografts attest to the validity of this concept.

The lack of regulation by the Food and Drug Administration in this era made it possible to redesign and try out valves quickly. There are those who believe that if the present stringent regulations governing valve development had been in force we would be many years behind our present position, although there were probably many patients who paid with their lives in return for rapid advances for others.

As complications became apparent, new designs were soon produced in an attempt to obviate newfound problems. Struts were covered with cloth so that clots would adhere to the cloth and a protective neo-intima would smooth over the interstices of the weave. But the wear and tear of a million beats every 6 weeks in the strange and destructive environment of the bloodstream broke down the cloth and caused new problems.

Soft discs were eroded by the struts but hard discs eroded the struts, so the materials were changed again. Pyrolite carbon, a space age material said to be second only to diamonds in hardness, was substituted for the softer plastics and Silastic. But, in the meantime, it became apparent that two early Silastic ball valves, the Starr valve (model 1200) and the Smeloff valve could withstand the stresses of prolonged use and did not have to be changed.

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Complications. Not long after the first valves were implanted in patients complications began to appear. Some of these had been anticipated; others had not. It was realized from the start that patients would have to take anticoagulant agents, but the possibilities of mechanical changes had not been fully realized, although extensive bench testing had been done. Bench testing was no substitute for in vivo experiments. Few dogs survived valve replacement, usually because the valve clotted in the first few weeks. Pigs, sheep and calves became the experimental animals because it was believed that their vascular systems or coagulation processes more closely approximate those of humans. Primates were too expensive.

Thromboembolism, thrombosis without embolism, paravalvular leakage, hemolysis, poppet embolism, ball variance, infection, cusp rupture and degradation, valve stenosis and functional gradients: the list of problems is long and not yet complete. But gradually, with changes in materials and design, the problems have become fewer, although they have not disappeared. Some will never disappear. Bacterial endocarditis is not primarily a problem of valve design, but perhaps its incidence can be reduced by constant vigilance. The same vigilance can reduce the complications of anticoagulants.

An outsider looking at this history might conclude that it is an account of meddlesome physicians experimenting without regard for the consequences. Nothing could be further from the truth. The amount of research, the dollars, time, effort and concern that have gone into the development of valves now available have been enormous. Perhaps the pace of changes has slowed, and rightly so. Cardiologists and surgeons have before them a choice of many good valves that have stood the tests of time and use. The urge and need for new designs is not as great as it was 10 or 20 years ago. The federal government has entered the fray, imposing regulations to guarantee that everything produced will, as nearly as possible, be free of problems.

Present status of prosthetic valves. The ultimate test of a valve has always been long-term survival of patients using the valve. As the years go by, the concept of "long term" itself changes. In the first few years reports described 1 and 2 year results. Then a few 5 year results appeared. And now we are in a position to look for a small number of 20 year results, many 10 year results and hundreds of 5 year results. Analyzing such long-term results introduces new problems. During the years under study the selection of patients, surgical techniques and skills and those undefinable changes that occur as surgeons become more experienced have been in a state of constant flux. Starr (2) has clearly demonstrated in his paper published in this issue that among his patients the results have improved in different time periods even though the operations they received were ostensibly the same.

We may never have definitive results. At best, we may be able to say to patients, "Here and now, with this valve, at your age and with your ventricular function, you have a certain percent chance of living 5 years, a different chance of living 10 years, and your chances of living without any complications are such and such. With your new valve you may have problems but we hope that the problems you have will be less serious than the problems you have had."

The papers presented in this and subsequent issues review the results with several valves. Some of the results presented cover many years, others only a few years; but, taken in toto, they represent a spectrum of choices now available to physicians and patients. Twenty-five years ago most of us thought that within a quarter century the major problems would be solved and we would have the "perfect" valve. That dream has not materialized and, more realistically, we now recognize that there is no perfect valve. Different patients have different needs. We need choices. The valve that is best for a 40 year old man with a sedentary job may not be best for a 70 year old woman who lives by herself and whose memory is not what it once was. The best valve for a child is not the best for all adults.

"The patient-valve interface index." But how is the clinician to choose what is best? Perhaps from this series of papers can be developed a patient-valve interface index. Such an index would take into account the many factors relevant to choice of a valve, such as clinical and laboratory data, immunologic and hematologic data, associated illnesses, potential pregnancy, age, job, activity level, body size, ability to take anticoagulants, psychologic status, and so on, assigning to each factor a numerical weight. These values could then be correlated with what is known about the performance profile of the different valves available. The final index would then indicate which valve or valves would be the best choices for that particular patient. Ultimately, the choice should be a joint decision involving the surgeon, the cardiologist and a *well informed* patient. Whatever changes there may be in the next quarter century, it is to be hoped that the procedure for choosing a valve for a particular patient will become more logical, resulting in the best of possible long-term results.

References

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2. Starr A. The Starr-Edwards valve. J Am Coll Cardiol 1985;6:899–903.